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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,342	04/14/2004	Nobert Hofgen	HUBR-1260-US	5382
24972	7590	12/22/2005	EXAMINER	
FULBRIGHT & JAWORSKI, LLP			MORRIS, PATRICIA L	
666 FIFTH AVE			ART UNIT	
NEW YORK, NY 10103-3198			PAPER NUMBER	

1625

DATE MAILED: 12/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/824,342	HOFGEN ET AL.	
	Examiner	Art Unit	
	Patricia L. Morris	1625	

**– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restriction

This application has been found to contain more than one invention. Therefore, restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-6, 13, 16 and 17, drawn to compounds, classified in classes 540, 544 and 546, various subclasses.
- II. Claims 7, 8, 14 and 18, drawn to multiple processes, classified in classes 540, 544, 514 and 546, various subclasses.
- III. Claims 9-12, drawn to multiple uses, classified in class 514, various subclasses.
- IV. Claims 15 and 19, drawn to compositions and methods containing an additional active ingredient, classified in class 514, various subclasses.

These inventions are distinct, each from the other because of the following reasons:

These distinct inventions have acquired separate status in the art, will support separate patents, and will require different fields of search for the respective inventions. Accordingly, restriction for examination purposes as indicated is considered proper; 35 U.S.C. 121; 37 CFR 1.141; 37 CFR 1.142.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP ̳

Art Unit: 1625

806.05(h)). In the instant case the products as claimed can be used in materially different processes as evidenced by applicants' own claims and specification.

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the products as made can be made by materially different processes as evidenced by applicants' own claims and specification.

Inventions I and IV are unrelated because invention I does not require an additional active ingredient for patentability.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

In the event of an election of either Groups I, III or IV, applicants are required to elect a single disclosed species representative of the claimed invention since the variations in R¹, R⁵, etc., encompass all heterocyclic chemistry classified in classes 540, 544 and 546, various subclasses. The staggering arrangement of possibilities does not permit classification of the claimed subject matter. Each heterocycle represents an independent and patentably distinct invention.

Should applicant(s) traverse on the ground that the species inventions identified are not patentably distinct, applicants should submit evidence or identify such evidence now of record showing the above identified species inventions to be obvious variants, or clearly admit on the

Art Unit: 1625

record that this is the case. In either instance, of traverse, if the examiner finds one of the inventions in the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

A Markush-type claim is directed to an independent and distinct inventions if two or more of its members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other member(s). In re Weber, 198 USPQ 330, footnote 3.

A reference to a pyrazine here would not be a reference to an imidazole. When one writes out the entire compound, as a whole, one arrives at patentably distinct heterocyclic compounds, along the lines indicated in the Groups of the first page of this action. Distinct, independent, heterocyclic nuclei.

Independent means the compound is capable of being utilized alone, not in combination with other compounds listed in the Markush expression; MPEP 802.01.

If the members are so diverse that they will support separate patents, *i.e.*, a reference for one would not constitute a reference for the other, then restriction is considered proper. MPEP 2173.05(h).

Claims 1-6, 13, 16 and 17 will be examined to the extent readable on the elected compounds.

In the event of an election of Group III, applicants are requested to elect a single disclosed method, *i.e.*, a specific disease.

In the event of an election of Group IV, applicants are requested to elect a single disclosed mixture, *i.e.*, compound plus specific active ingredient.

Art Unit: 1625

In, In re Weber, 198 USPQ 332, In re Hengehold, 169 USPQ 473, was noted for the proposition that as long as applicants have maintained the right (as they do here) to file the non-elected subject matter in divisional applications, then restriction is proper, as to that point.

Applicant may file the divisional subject matter noted in divisional applications. If applicant wishes a generic expression of the elected invention the claims here need be amended to reflect that election.

This restriction requirement is being written as previous experience has indicated that with Foreign applicants and the inherent time delays, applicants' representative is better able to make an informed, correct, election of the invention applicants would wish to have prosecuted here if applicants are given the opportunity to see the restriction requirement laid out, and given the time to make an informed decision.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

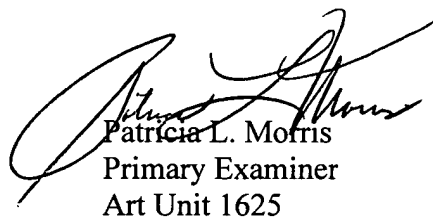
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia L. Morris whose telephone number is (571) 272-0688. The examiner can normally be reached on Mondays through Fridays.

Art Unit: 1625

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Patricia L. Morris
Primary Examiner
Art Unit 1625

plm
December 14, 2005